

# Medtronic Mechanical Circulatory Support (formerly HeartWare Inc.) Expands Recall for Ventricular Assist Device Controllers and DC Adapter

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death*

## Recalled Product:

- HeartWare Ventricular Assist Device (HVAD) Controllers
- Serial Numbers: All HeartWare Controllers
- Product Codes: 1400, 1401, 1403, 1407, and the additional code 1435 for the HVAD DC adapter
- Manufacturing Dates: March 1, 2006 to December 1, 2016
- Distribution Dates: October 11, 2006 to December 1, 2016
- Devices Recalled in the U.S.: 8,343

## Device Use:

The HeartWare Ventricular Assist Device (HVAD) helps deliver blood from the heart to the rest of the body. It is used in patients who are at risk of death from end-stage left ventricular heart failure and who are waiting for a heart transplant. The system includes a pump implanted in the space around the heart (pericardium (<https://medlineplus.gov/ency/imagepages/18081.htm>)). It also includes a driveline cable that goes through the skin. The driveline connects the pump to an external controller that regulates the speed and function of the pump. The system is powered with batteries or power adapters. The HVAD is designed for use both in and out of hospital settings, including during patient transport.

## Reason for Recall:

Medtronic Mechanical Circulatory Support is expanding this recall to include an additional product code and instructions to exchange recalled products.

The company recalled (<https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm529488.htm>) the HVAD controller due to a loose power connector which may cause the rear portion of the pump's driveline connector to become separated from the front portion of the driveline connector. A loose connector may allow moisture to enter the controller causing corrosion, electrical issues,

reduced speaker volume and connection failures. If the speaker volume is decreased, the patient may not hear the alarm. If there is a loss of connection, the pump may stop which could cause serious adverse health consequences, including death.

**Who May be Affected:**

- Patients receiving cardiac support using the HVAD system
- Health care providers and caregivers monitoring patients with a HVAD system

**What to Do:**

Since the issuance of the November 2016 [recall](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm529488.htm) (<https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm529488.htm>), Medtronic Mechanical Circulatory Support has developed an updated HVAD controller and power management software to address the power connector issues. The FDA approved the updated controller on April 7, 2017. The company has initiated procedures for the exchange of previous generations of HVAD controllers and adapters for the updated controller system.

On January 3, 2017, Medtronic Mechanical Circulatory Support sent an “Urgent Field Safety Notice” asking consumers to:

- Review the notice and forms, and to forward the notice to other staff within their organizations for their awareness;
- Complete, sign, and return the “Acknowledgement Form” to Medtronic Mechanical Circulatory Support within 30 days of receipt of the letter;
- Complete training that will cover the new product labeling including the instructions for use and patient manual;
- Quarantine and replace affected HVAD controllers, DC adapters, instructions for use, emergency responder guides and patient manuals in hospital inventory after training is complete;
- Notify and schedule each of their patients as soon as possible for an appointment to exchange their controllers;
- Return all quarantined HVAD controllers and DC adapters to Medtronic Mechanical Circulatory Support; and
- Once the affected product in inventory has been identified and returned, complete and return the attached “Completion Form” to [con2.0@medtronic.com](mailto:con2.0@medtronic.com) (<file:///C:/Users/Adam.Saltman/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/BPWXHJX2/con2.0@medtronic.com>) or their Medtronic Mechanical Circulatory Support representative no later than 12 months from the date of the letter according to the instructions on the form.

**Contact Information:**

Health care providers who have questions should contact Medtronic Mechanical Circulatory Support at [con2.0@medtronic.com](mailto:con2.0@medtronic.com) (<file:///C:/Users/Adam.Saltman/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/BPWXHJX2/con2.0@medtronic.com>) or at 305-364-1402 with any questions related to this recall.

**Date Recall Initiated:**

February 3, 2017



### Additional Resources:

Medtronic [Press Release \(http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2262696\)](http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2262696)

### How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) either online, by regular mail or by FAX to 1-800-FDA-0178.

[More in Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](#)

[2017 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](#)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](#)